

Comparison of extra-peritoneal and intra-peritoneal cesarean technique: a prospective randomised trial

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Summary

Objective: Comparison of extra-peritoneal cesarean (EPC) and intra-peritoneal cesarean (IPC) section in terms of postoperative pain, pulmonary function, fever, gastrointestinal function, and other maternal and fetal morbidities. **Materials and Methods:** Fifty patients were included in this prospective study. All patients' demographic data such as blood count, gestational week, height, weight, body mass index, and age were recorded in the preoperative period. Forced vital capacity, forced expiratory volume at second 1, and peak expiratory flow values were measured before and 24 hours after the operation. Pain was evaluated using visual analog scale (VAS). Time from the beginning of the operation to the delivery, total operation time, birth weight, and Apgar scores were also recorded. Changes in pulmonary function tests, VAS, time to hear bowel sounds, gas and stool discharge times, leukocyte increase rate, fever, and C-reactive protein values were compared between the groups. **Results:** Lower abdominal and incision pain were less in the EPC group ($p < 0.05$). Inflammatory response was lower and bowel sound were heard earlier in the EPC group ($p < 0.05$). **Conclusion:** EPC section seems to be advantageous in terms of postoperative pain, pulmonary function, intestinal function, and febrile morbidity. Further studies with larger populations are needed in order to recommend this technique routinely.

Key words: Cesarean section; Complications; Extra-peritoneal cesarean; Pulmonary function test; Visual analog scale.

Introduction

Cesarean section is the most common abdominal surgery worldwide [1]. In standard cesarean section technique, accessing the peritoneal cavity entails manipulation of the intestines and irritation of the peritoneal cavity by blood, amniotic fluid, and vernix which leads to postoperative morbidity including pain, nausea/vomiting, intestinal dysfunction, voiding disorders, adhesion, and infertility [2-4]. Postoperative pain is especially a frequently seen morbidity that may be associated with the disruption of patient comfort, as well as pulmonary complications (atelectasis, etc.) [5]. To reduce the morbidity of classical transperitoneal cesarean technique the extra-peritoneal cesarean (EPC), approach was introduced [6, 7]. Historically, EPC was used in pre-antibiotic era since it prevents dissemination of intrauterine infections to the peritoneal cavity [8]. After antibiotics became easily accessible and prophylaxis was introduced, this method was rarely performed. There is limited data on its advantages other than prevention of the spreading of infections [9].

In this study, the authors aimed to compare the EPC technique with intra-peritoneal cesarean (IPC) in terms of postoperative pain, pulmonary function, fever, gastrointestinal function, and other maternal and fetal morbidities.

Materials and Methods

This randomized, controlled, single blinded prospective study was conducted in the Department of Obstetrics & Gynaecology, in Zeynep Kamil Maternity and Children Hospital, between March 2016 and June 2016. It was approved by the local ethics committee (no. 56) and written consent was obtained from all 50 participated patients.

All cases undergoing elective and emergency cesarean section, at 38-40 weeks of gestation, were included in the study. Exclusion criteria were patients with induced labor pain, with premature rupture of membranes, with any infection (urinary, pulmonary, etc.), preoperative fever of 37 degrees centigrade or higher, diagnosed with pulmonary disease (asthma, chronic obstructive pulmonary disease, pneumonia, bronchitis, etc.), preoperative blood leukocyte value of 10,000 or higher, with suspected abnormal placenta (accreta, increta, percreta), and patients having risk of pelvic infection (urinary system infection, premature rupture of membrane) in the preoperative period.

The patients were blinded to the surgical technique that they would undergo. Two groups were determined using a random number table and the surgeons who were experienced in EPC and oncologic surgery were informed about the type of technique that they would apply just before the surgery in the operating room. The physician who assessed and recorded the primary and secondary outcomes had no information about which technique was applied to which patient.

Preoperative antibiotics were given to all patients before beginning the procedure. The patients were administered spinal or



Figure 1. — Blunt dissection continuing downwards. Bladder and parietal peritoneum are separated from each other.



Figure 2. — Uterus after extraperitoneal section is completed.

general anesthesia according to their requirements. EPC was performed as described by Shinde *et al.* [10]. Following pfannenstiel incision, the rectus sheath was incised transversally and rectus muscles and transversalis fascia were separated. The parietal peritoneum which was attached to the dome of the bladder was separated by blunt dissections to expose the lower uterine segment and the paravesical space was exposed to locate the vesicouterine fold (Figure 1). The uterus was incised transversely and delivery was carried out (Figure 2).

All patients' blood count, gestational week, height, weight, body mass index (BMI), and age were recorded in the preoperative period. Forced vital capacity (FVC), forced expiratory volume in second 1 (FEV 1), and peak expiratory flow values (PEEF) were measured with a spirometry device before and 24 hours after the operation. During the measurement with spirometry, patients were positioned reclining at 45 degrees to the horizontal plane. Pain in the right and left shoulders, upper and lower quadrant of the abdomen, and incision was evaluated using visual analog scale (VAS) at postoperative hours 0, 6, 12 and 24. Full blood count and C-reactive protein (CRP) were studied at 24 hours postoperatively and oral fever was measured at the same time. Bowel sounds were monitored in all patients with a stethoscope at postoperative period. Gas and stool discharge times and numbers were recorded. In addition, time from the beginning of the operation to the delivery of the infant, total operation time, birth weight, and Apgar scores were also recorded. Changes in pulmonary function tests and in hematocrit and leukocytes between preoperative and postoperative measurements were recorded. All patients were administered standard 75 mg diclofenac once every 12 hours.

Besides demographics, the two groups were compared in terms

of change in the rate of pulmonary function, hemoglobin, hematocrit, leukocytes and platelets, discharge time, gas and stool discharge, time to the first heard intestinal sound, postoperative febrile morbidity, CRP, and in terms of regional pain.

Sample size: in a study by Tappauf *et al.* [11], pain scale values in the first 24 hours were found to be 3.00 (2.33-3.67) and 3.67 (2.67-5.00) with EPC and IPC methods, respectively. Utilizing these values, in this study, the minimum sample size for each group was calculated to be at least 24 persons with 80% power and 0.05 type I error (R 3.0.1. open source program).

Statistical evaluation of the data was done with SPSS for v. 11.5 software. Comparisons between the two groups were made using Student's *t*-test, Mann-Whitney U test, and Fisher-Exact test. A value of $p < 0.05$ was considered statistically significant.

Results

Twenty-five patients in the intraperitoneal group and 25 in the extraperitoneal group were analyzed (Figure 3).

Primary outcomes: examining VAS scores, the pain score was similar for the shoulder and abdominal upper quadrant ($p > 0.05$), while the pain score of the abdominal lower quadrant and incision were significantly higher in the IPC group from the zero hour through the 24th hour ($p < 0.05$) (Table 1).

Secondary outcomes: preoperative PEEF values were higher in the IPC group ($p < 0.05$), while the other two pul-

Table 1. — Pain scores of the groups according to body parts.

	Hours	Extra-peritoneal (n=25)	Intra-peritoneal (n=25)	p
		Median (min.-max.)	Median (min.-max.)	
Right shoulder	0	0(0-0)	0(0-2)	0.153
	6	0(0-5)	0(0-2)	0.588
	12	0(0-0)	0(0-1)	0.153
	18	0(0-0)	0(0-1)	0.153
	24	0(0-0)	0(0-1)	0.317
Left shoulder	0	0(0-0)	0(0-2)	0.153
	6	0(0-5)	0(0-2)	0.588
	12	0(0-0)	0(0-1)	0.153
	18	0(0-0)	0(0-1)	0.153
	24	0(0-0)	0(0-1)	0.317
Upper abdominal quadrant	0	0(0-5)	0(0-4)	0.332
	6	0(0-1)	0(0-3)	0.563
	12	0(0-0)	0(0-3)	0.077
	18	0(0-1)	0(0-3)	0.284
	24	0(0-1)	0(0-3)	0.525
Lower abdominal quadrant	0	0(0-7)	2(0-7)	0.026
	6	0(0-4)	2(0-6)	0.045
	12	0(0-4)	0(0-5)	0.029
	18	0(0-3)	0(0-5)	0.045
	24	0(0-2)	0(0-5)	0.068
Incision	0	4(0-8)	7(3-8)	0.001
	6	2(0-6)	5(2-7)	0.001
	12	1(0-5)	4(2-7)	0.001
	18	1(0-5)	3(1-7)	0.001
	24	1(0-4)	3(1-7)	0.001

monary test parameters were similar between the groups ($p > 0.05$). Postoperative values of these three parameters decreased compared to the preoperative values; however, this decrease was more significant in the IPC group ($p < 0.05$) (Table 2). Hemoglobin, hematocrit, platelet, and leukocyte values were similar between pre- and postoperative periods ($p > 0.05$) (Table 2). The postoperative increase of leukocytes was more significant in the IPC group ($p < 0.05$), while changes in hemoglobin, hematocrit, and platelet were similar ($p > 0.05$) (Table 2). The delivery and total operation time were shorter ($p < 0.05$), whereas fever and CRP values were higher in the IPC group ($p < 0.05$) (Table 3). Again, gas discharge and bowel sounds were heard earlier in the EPC group ($p < 0.05$). Infant weight, Apgar scores, discharge, and stool discharge times were not found to be statistically different between the two groups ($p > 0.05$) (Table 3). The need for additional analgesia was higher in the IPC group ($p < 0.05$) (Table 3).

Discussion

This prospective, double-blinded study demonstrated that pain score was less, especially at and around the site of incision; impairment in pulmonary tests was lower, return of intestinal motility was earlier, and inflammatory response was less in patients undergoing EPC section ($p < 0.05$).

Only a few studies in the literature reported outcomes of

EPC and almost all of these data belong to the 1940s to 1980s [11-17]. The studies mostly discussed this issue technically and emphasized that these patients heal quicker and require less analgesia. On the other hand, it has been stated that there is insufficient experience to routinely perform this technique [14-17]. In the present study, VAS scores in and around the surgical site were significantly lower in the EPC group from the postoperative zero hour to the 24th hour ($p < 0.05$). In addition, the need for additional analgesia was lower in this group ($p < 0.05$). Alleviating pain provides more comfort to the patient, as well as allowing quick mobilization and early discharge [11]. Tappauf *et al.* [11] reported that both shoulder and surgical site pains were lower in an EPC group. Besides skin incision pain, opening of the parietal peritoneum caused irritation, with blood and amniotic fluid exacerbating pain [2-4]. The pain negatively affects pulmonary function in the postoperative period, which leading to postoperative pulmonary complications [18, 19]. Technique factors such as the type of anesthesia (general, regional), type of incision, and surgical technique have a direct effect on the development of the complications [20]. Since diaphragmatic dysfunction is minimal during lower abdominal surgeries, pain is stated as the most important factor in the disruption of pulmonary function in the postoperative period [21]. Decrease in pulmonary capacity and volume, decrease in FVC and FEV 1, and FEV1/FVC ratio are among these changes [21, 22]. In cases

Table 2. — Pulmonary function test and hemogram parameters of the groups.

		Extra-peritoneal (n=25)	Intra-peritoneal (n=25)	p
FVC mean±SD	Preoperative	3.16±0.59	2.90±0.45	0.090
	Postoperative	2.86±0.58	2.11±0.56	0.001
	Difference	0.30±0.18	0.79±0.42	0.001
FEV 1 mean±SD	Preoperative	2.77±0.40	2.78±0.35	0.964
	Postoperative	2.43±0.52	2.02±0.49	0.006
	Difference	0.40±0.33	0.76±0.39	0.001
PEEF mean±SD	Preoperative	4.85±1.24	5.73±0.99	0.008
	Postoperative	3.45±0.92	3.63±1.12	0.523
	Difference	1.40±1.04	2.10±1.00	0.021
HGB mean±SD	Preoperative	11.63±1.22	11.49±1.40	0.705
	Postoperative	10.12±1.35	10.22±1.31	0.803
	Difference	1.50±0.91	1.27±0.59	0.282
HCT mean±SD	Preoperative	34.94±2.90	34.30±3.67	0.495
	Postoperative	30.44±3.84	30.32±3.45	0.911
	Difference	4.50±2.75	3.98±1.67	0.423
WBC mean±SD	Preoperative	9768±1877	9576±1907	0.721
	Postoperative	11394±2266	12598±2573	0.086
	Difference	1627±1489	3022±2043	0.008
PLT mean±SD	Preoperative	216480±58970	240000±89306	0.277
	Postoperative	188416±55631	215360±72931	0.148
	Difference	31304±24511	26080±30833	0.510

of well-administered postoperative analgesia or local anesthetic application on incision, increases may be observed in vital capacity and pulmonary function [23]. With EPC performed without opening of the parietal peritoneum, pulmonary functions are less affected as a result of less distention since the intra-peritoneal cavity is not filled with air. In classical IPC, irritant substances such as amnion and blood may reach the diaphragm, negatively affecting pulmonary function due to diaphragm irritation. In the present study, FEV1, FVC, and PEEF values were significantly decreased in the postoperative period in both groups. Nevertheless, the decrease in FEV 1, FVC, and PEEF values

compared to the preoperative period was lower in the EPC ($p < 0.05$). Similar to the results from the aforementioned study, when the peritoneal cavity was not entered, pulmonary functions were better, because blood, amnion fluid or air did not negatively affect diaphragmatic functions.

Postoperative febrile morbidity has been described as an oral temperature of 38 degrees or higher measured at four-hour intervals except in the first 24 hours [24]. Although its frequency has been reduced with the use of prophylactic antibiotics, it may nevertheless be seen at a rate of 20% following cesarean section [25]. In a study by Shinde *et al.* [13] comparing modified EPC and classical cesarean, febrile morbidity was significantly lower in the EPC group. Ding *et al.* [26] also observed that febrile morbidity was significantly lower in a group that underwent EPC (10% versus 24% $p < 0.01$), which underscores that this method can be safely used, especially in patients having a risk of intrauterine infection (e.g. emr). With the worldwide increasing resistance to antibiotics, postoperative febrile morbidity may be an important problem, particularly in rural areas [13]. For such areas, EPC may be favorable. In the present study, there was no febrile morbidity in all of patients. However mean postoperative temperature was lower in the EPC group ($p < 0.05$). Again, the postoperative leukocyte increase and increase in CRP values after 24 hours compared to preoperative values were lower in the EPC group ($p < 0.05$). This may be explained by a lower inflammatory response, following direct contact with substances such as amnion and blood that spread into the peritoneum or peritoneal cavity, with air and may contribute to postoperative febrile morbidity.

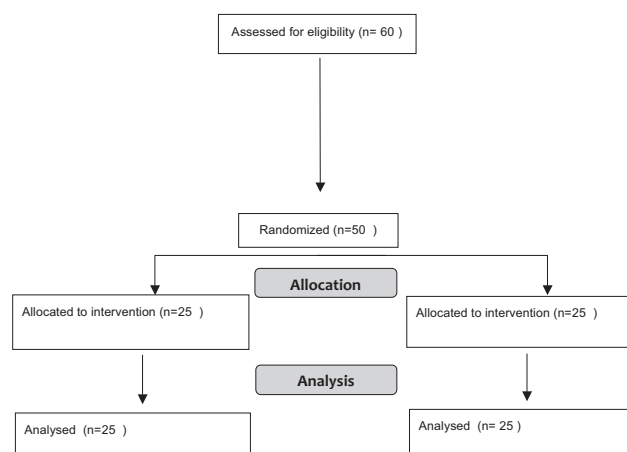


Figure 3. — Flow diagram of trial recruitment.

Table 3. — Characteristics of the patients and perioperative parameters.

	Extra-peritoneal (n=25)	Intra-peritoneal (n=25)	P
BMI mean±SD	30.01±4.40	30.23±4.13	0.855 ^a
Gravid median (IQR)	3 (1)	2(1)	0.707 ^b
Gestational week mean±SD	38.96±0.89	38.12±1.72	0.036 ^a
Opening the retzius space n(%)	9(36.0)	0(0.0)	0.002 ^c
Delivery time mean±SD	7.60±2.10	3.04±1.40	0.001 ^a
Operation time mean±SD	26.96±7.92	21.48±3.45	0.003 ^a
Infant weight mean±SD	3282±433	3194±697	0.593 ^a
Apgar 1' median (IQR)	8(1)	8(0)	0.163 ^b
Apgar 5' median (IQR)	9(0)	9(0)	1.000 ^b
Temperature	36.54±0.24	36.72±0.34	0.036 ^a
C-reactive protein	3.42±1.71	5.58±4.31	0.024 ^a
Bowel sound mean±SD (medyan)	63.00±50.74(60.00)	88.80±46.22(60.00)	0.005 ^b
Discharged time mean±SD (medyan)	40.32±10.89(48.00)	43.20±12.00(48.00)	0.348 ^b
Gas discharge time mean±SD (medyan)	11.96±5.48(10.00)	19.24±9.60(17.00)	0.003 ^b
Stool discharge time mean±SD (medyan)	22.16±5.09(22.00)	24.84±9.45(25.00)	0.340 ^b
Ileus n(%)	0(0.00)	0(0.00)	—
Additional analgesic doses median (min.-max.)	0 (0-2)	0(0-4)	0.014 ^b

a: Student's *t*-test. b: Mann-Whitney *U* test. c: Fisher-Exact test.

Following abdominal surgery, intestinal and gastric motility returns to normal within 12 to 24 hours [27]. Manipulation of the intestines, use of gas or compression, suturing the peritoneum, and spreading of amniotic fluid and blood to the cavity during surgery all affect intestinal motility [28]. Early onset of gastrointestinal system function allows patients to tolerate early oral nutrition, which is associated with earlier healing and discharge [29]. In this study, bowel sounds were listened with a stethoscope to evaluate motility. Intestinal sounds were heard and gas discharge occurred earlier in the EPC group ($p < 0.05$). Similarly, Shinde *et al.* [13] stated that intestinal motility and discharge time were earlier in an EPC group. In the present study, no significant difference was found in discharge times between the groups ($p > 0.05$). This may be attributed to several reasons. First, since the number of patients in the groups was relatively small and no significant complications were seen in either group, there were no patients requiring longer stay in the hospital. Second, patients who underwent cesarean section were not discharged before 48 hours according to hospital policy, hindering early discharge of potential subjects in the EPC group, and thus difference statistics could not be performed between the two groups.

In the present study, no significant difference was found between the groups in terms of infant weight and Apgar scores ($p > 0.05$). However, delivery and total operation time were longer in the EPC group ($p < 0.05$). Similarly, in the study by Shinde *et al.* [13] delivery time was longer in the EPC group ($p < 0.01$), but Apgar scores were similar ($p > 0.01$). In their study investigating the relationship between delivery time and Apgar scores, Anderson *et al.* [30] found no correlation between time and Apgar scores. The present authors attribute the longer time in the EPC group directly to the technique being more difficult. They believe

that EPC would be quicker and safer in the hands of naturally experienced physicians. In this study, all patients were assessed by a single physician (MBS) who has been experiencing a certain learning curve. During the study period, complications such as bladder damage or bleeding were not observed, only the opening of Retzius' space was commonly seen ($p < 0.05$). The present authors thought that complications in the technique in which the bladder can easily be reached laterally without opening the paravesical area, are similar to the classical method.

The limited number of subjects in both groups may be regarded as a limitation of the study. Additionally, the number of studies investigating this technique is limited, making this study valuable.

Conclusion

Considering the increasing antibiotic resistance, especially in rural areas and its effects on other morbidities, and hospitalization time, EPC technique may be advantageous. Reduction of morbidity and mortality seems to be crucial after cesarean section, which is the most common abdominal surgery worldwide. Further studies with larger series are needed in order to recommend this technique routinely.

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